HENRY A. WAXMAN, CALIFORNIA
CHAIRMAN

TOM DAVIS, VIRGINIA
RANKING MINORITY MEMBER

ONE HUNDRED TENTH CONGRESS

Congress of the United States

House of Representatives

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
2157 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515–6143

Majority (202) 225–5051
Minority (202) 225–5074

February 13, 2007

Daniel Vasella, MD
Chairman and CEO
Novartis
Novartis International AG
CH-4002 Basel
Switzerland

Dear Dr. Vasella:

It has come to my attention that major international health organizations are deeply concerned about a position Novartis has taken in litigation in India. According to these organizations, when a Novartis patent application was denied, instead of simply appealing the rejection, Novartis challenged the public health safeguards in India's patent law.

I do not dispute your right to apply for a patent or appeal a denial. I am concerned, however, that your attempt to influence domestic Indian law could have a severe impact on worldwide access to medicines.

India's robust generics market supplies affordable, essential drugs both to its citizens and to poor nations around the world. Its law contains safeguards designed to preserve a balance between protecting innovation and promoting public health. If India is pressured to make its patent laws more stringent than its obligations under international trade law, this crucial supply of medicines could be threatened. Whatever the outcome of the case, the appeal could have a chilling effect, as countries contemplating public health safeguards in their patent laws fear they will be challenged by the pharmaceutical industry.

Because of the profound need for affordable medicines in the developing world, I am writing to urge you to reconsider Novartis's challenge of public health safeguards in India's patent law.

India's Generic Industry

Nearly 80% of India's population lives on less than $2 a day. But the country has a robust generic pharmaceutical industry that has for decades provided affordable drugs for its citizens. The industry also creates generics for export to most of the world's poor countries, most of which lack any domestic manufacturing capacity.

It is hard to overstate the role that India plays in manufacturing affordable drugs for those who most need them. India exports two-thirds of its production to developing countries. Indian companies produce 50% of the essential drugs UNICEF provides to children worldwide, and 80% of the antiretroviral drugs that Doctors Without Borders gives to HIV patients.[1] Furthermore, all but three of the 36 generic AIDS drugs approved by the FDA for the U.S. global AIDS program are produced in India.[2]

In 2005, India amended its patent laws to comply with its international trade obligations. Because countries are permitted certain flexibilities in implementing and interpreting their obligations, India also included amendments that provide public health safeguards so that patents do not unnecessarily restrict access. For example, the new law does not allow patents for a "new form" of a known substance unless it demonstrates an enhancement of "efficacy." [3]

The Novartis Case

In 2005, the Indian Patent Office rejected Novartis's application for a patent for the cancer drug Gleevec.[4] The rejection was based on India's legal requirement that new forms of a substance can only be patented if they demonstrate higher efficacy. Because a different form of the drug had already been on the market in India, Novartis would have had to prove that the new

---

[1] Medecins sans Frontieres (Doctors Without Borders), *Examples of the Importance of India as the "Pharmacy for the Developing World"* (Jan. 29, 2007) (online at www.accessmed-Msf.org/documents/Overview%20Jan%202007%20FINAL.doc).

[2] FDA, *President's Emergency Plan for AIDS Relief, Approved and Tentatively Approved Antiretrovirals in Association with the President's Emergency Plan* (online at www.fda.gov/oia/pepfar.htm) (accessed Feb. 9, 2007).

[3] 1970 India Patent Act, 2005 Amendments, §3(d).

[4] V. Rengasamy, Asst. Controller of Patents and Designs, Decision re: Novartis AG, Switzerland, The Applicant; Natco Pharma Ltd., India, The Opponent (Jan. 25, 2006). Gleevec (imatinib mesylate) is sold as Glivec in the United States.

form resulted in enhanced efficacy. The Patent Office found that Novartis had not proven this claim.[5]

Instead of simply appealing the rejection, however, Novartis is challenging the public health safeguards of the law itself.[6] If successful, the Novartis position could threaten access to medicines in India and beyond.

The grounds for the Novartis challenge are questionable. In 2001, 142 countries, including the United States, declared that international intellectual property obligations "can and should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health, and in particular, to promote access to medicines for all."[7]

India's law does appear to protect innovation, by providing for 20-year patent protection for innovative products. Moreover, even if India's patent laws fall short of the wishes of the pharmaceutical industry, patentholders continue to enjoy stringent protections in the United States and other wealthy nations, where they make the bulk of their profits. Both Indian and non-Indian firms may take advantage of the patent laws in these wealthy countries, regardless of India's laws. Your company, for example, reported to the SEC that 84% of net pharmaceutical sales in 2006 were in the United States, Europe, and Japan.[8]

Novartis only reinforces this point when it notes that 99% of patients taking Gleevec in India receive the drug for free because they cannot afford it.[9] Such examples of corporate generosity are laudable where effective and accessible, but reliance on corporate largesse is not a sustainable answer. In pursuing the tiny slice of the market with the money to afford its drugs, Novartis may be threatening future access to medicines for the vast majority of Indians who live in poverty — and their counterparts around the world.

---

[5] *Id.*

[6] Novartis, *In the High Court of Judicature at Madras (Special Original Jurisdiction) W.P.NO.24759 of 2006.*

[7] Paragraph 4, 'Declaration on the TRIPS Agreement and Public Health', WTO Ministerial Conference — Fourth Session, WT/MIN(01)/DEC/2, adopted 14 November 2001. (Doha Declaration).

[8] Novartis, *US Securities and Exchange Commission Form 20-F 2006*, p. 48.

[9] *The Novartis Perspective: Improving Indian Patent Law Helps Patients and Societies* (Jan. 22, 2007) (online at www.novartis.com/downloads/about-novartis/Novartis_position-Glivec_Gleevec_patent_case_india.pdf).

Conclusion

Novartis and its colleagues in the pharmaceutical industry should respect countries' rights to take measures that balance the protection of innovation and the promotion of public health. I urge you to reconsider your position in this case.

Sincerely,

Henry A. Waxman
Chairman